EXHIBIT 1

To: Elizabeth Holmes[eholmes@theranos.com]
Cc: Sunny Balwani[sbalwani@theranos.com]
From: Daniel Young
Sent: Sat 4/12/2014 6:25:44 AM
Importance: Normal
Subject: RE: Follow up to previous discussion
Received: Sat 4/12/2014 6:25:48 AM

My comments are below in red. Please let me know if you have further thoughts or want to discuss any of this. Thanks.

From: Elizabeth Holmes
Sent: Friday, April 11, 2014 4:35 PM
To: Daniel Young
Cc: Sunny Balwani
Subject: FW: Follow up to previous discussion

Take a look at this. Let me know where all this data is from/what the data is, whether you had exchanges with him in which he forwarded marketing articles, and also comments line by line on the below.

Separately re: marketing articles, I believe you already talked to him about the fact that what people are writing about our infrastructure is its longitudinal power in the context of lab to lab variability?

From: Tyler Shultz
Sent: Friday, April 11, 2014 3:38 PM
To: Elizabeth Holmes
Subject: RE: Follow up to previous discussion

Hi Elizabeth,

In my meetings with Daniel I found that the discrepancies between our CVs were due to Daniel calculating CV based on the median value of each precision run, while I was calculating CV of the entire data set for each level. When I asked him why we do this, he said that it was a way to average out the noise. I was under the impression that the coefficient of variation was meant to be, at least in part, a measure of how much noise exists in the data. By averaging out this noise before CV is calculated, the CV as a metric of assay performance becomes less meaningful. And because our calculations of CV are based on median rather than mean, this means that 2/3 of our data is entirely ignored both when calculating CV and acquiring a patient result.

Calculating the median does not ignore any data. It is statistical metric taking into account all the data. For one assay, we found the median to perform better than the mean. All other assays use the mean across the different tips. But that aside, Tyler still just does not grasp the meaning of the CV. There is no reason to report the CV of each individual tip for our assay. We happen to be running 6-tips (or six replicates) inside the device, but this what goes on inside the device really should be black box to the end user. The final reported result is all that matters. It is important for us (ie, R&D) to know tip to tip variance, but not relevant in terms of how we quantify assay precision (CV). I went over this in detail with Tyler before, as he was calculating this incorrectly before, but he still seems set this incorrect interpretation.

While I understand that calculating CV based on the medians is relevant for comparing our system to systems of our competitors, the fact that the CV of our cutoff level for Syphilis RPR drops from 43% to <20% by moving from CV of the entire dataset to CV of the medians tells me that a significant portion of our data is just noise. I believe that we should set two standards of CV that must be met in order for an assay to pass precision testing; a standard for the medians of each run, and a standard for each level's dataset as a whole.

Again, the variance across tips is not relevant - the variance for the reported value is what is quantified to assess assay performance.

Daniel also told me that for qualitative assays such as Syphilis RPR, the CV as metric of assay performance is less important than it would be for quantitative assays. I agree with him, at the end of the day the only thing that's important is delivering the correct result to our patients. However, given the high variation in our dataset, it is not surprising that when using a strict antibody index cutoff value of 1, our sensitivity was only 65% the first time we tested clinical samples and 80% the second time. The first issue I have with this is that there is no penalty for repeating an experiment. We repeat and delete rather than repeat and add. In our validation reports there is never any mention of how many attempts of precision or comparability testing it took to get the data that's presented. The second problem that I have is that our equivocal zone is adjusted and widened until we see the sensitivity and specificity that we want to report. Almost regardless of what the data looks like, we can adjust this zone until we get the 95% sensitivity that we want to see. Tellingly, out of the 247 patients that we tested, 66 of whom were Syphilis positive, more patients fell into our equivocal zone than we correctly diagnosed as being positive for Syphilis.

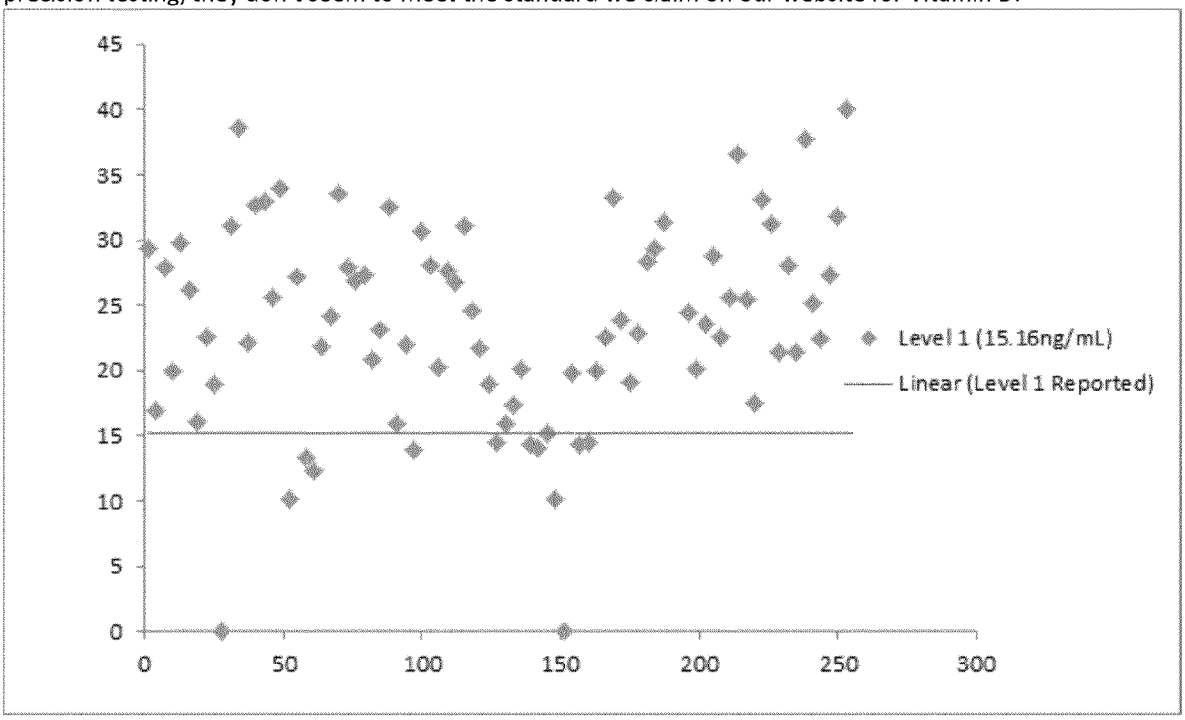
He makes it sounds like something inappropriate is being done, which it is not. Equivocal zones are commonly used, and expected in such qualitative assays. The approach being used for setting ours was based on common techniques. That being said, I do that our equivocal range is wider than I would like. The impact is that more patients will need confirmatory testing.

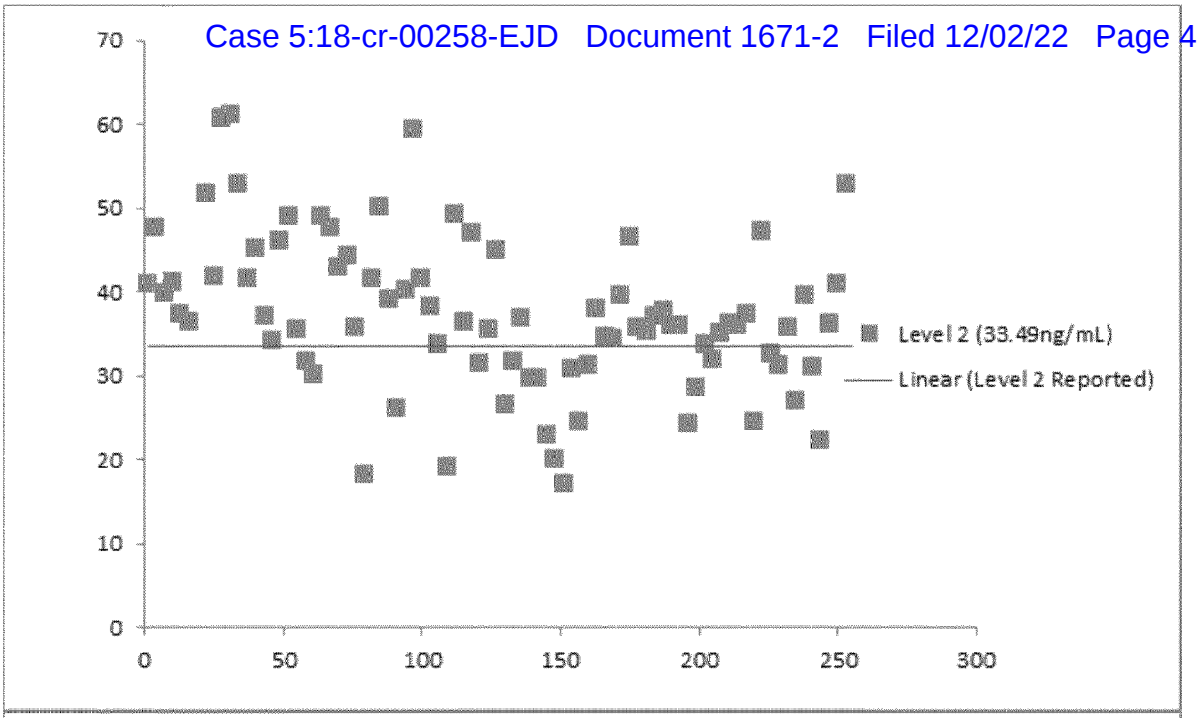
I don't know that any study was simply repeated with the original data being ignored. There have been times when the initial data was not good enough. The chemistry team then was asked to identify the root cause and make a change. And then the study was repeated.

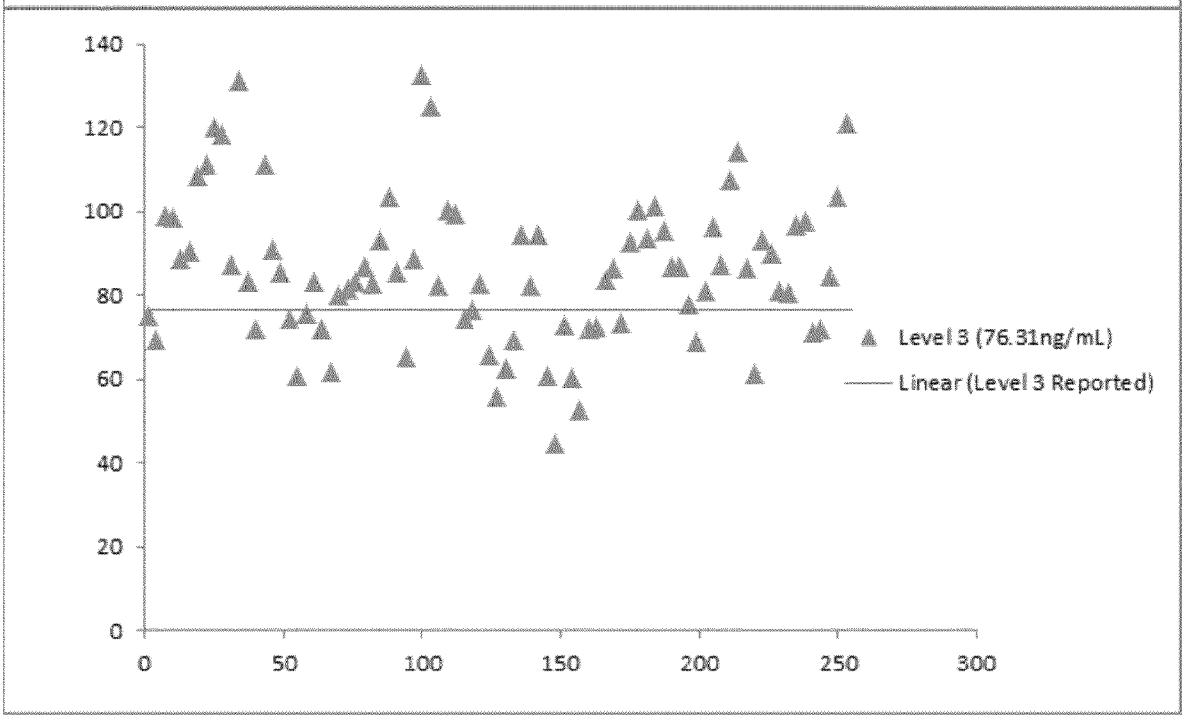
I then asked Daniel if he thought our Syphilis test was truly the most accurate and most precise Syphilis test on the market. He said that Theranos does not claim to have the most accurate or precise tests, and that if I could find any marketing materials that make such claims that I should forward them to him. A quick google search yields a handful of articles that explicitly make these claims. Daniel agreed that the authors make sweeping statements about our assay performances, but noted that Theranos never directly made any of these claims. If well-established institutions such as the Wall Street Journal have published misinformation about Theranos, it seems it would be in our best long-term interest to correct this information in order to uphold our image of bringing transparency to blood testing.

I did note to Tyler that Theranos will have a superior product by controlling/monitoring/reducing variance across our country-wide infrastructure. This will enable us to track/trend tests results for patients in a much more robust manner compared to what is available now to patients. Moreover, I explained that the precision studies done by other companies are typically limited in terms of well controlled experiments across a few sites. But in practice, across different labs, performance is known to be much worse. I will attach below the media excerpts that he had sent me.

I then thought back to our previous discussion when I asked about our claim of having <10% CV for our assays. We checked the Theranos website together and found that we only make this claim for Vitamin D. I checked the 2-Tip validation data (we were running 2-tip protocol at the time) and found that the CVs for our three levels were 18%, 16%, and 19% when calculated based on the median of each precision run and 23%, 23%, and 25% when calculated based on the entire dataset. Here are scatter plots of the results from VitD precision testing, they don't seem to meet the standard we claim on our website for Vitamin D.







Median was not used here – averages are.

For a while I've been giving our assays the benefit of the doubt until we see how the new 6-Tip method performs. Here is a comparison of the 7 assays we run on Theranos devices to their predicate methods. While we are now performing better than we were with the 2-Tip method, you can see that of the 7 assays we run on the Theranos system, there is only one level from one assay that shows less variation than our competitor's technology.

His Theranos TSH precision numbers do not match the validation reports. I am not sure if this is because he is calculating them himself, and using median, etc. That being said, our precision is still not as good as the Immulite for TSH. This is not new – we have discussed going back to some of these assays (such as TSH and PSA) for which we would like to increase performance, and create a next generation Theranos assay.

Immulite 3rd generation TSH	Theranos TSH

level (uIU/ml)	total CV
0.016	12.5%
0.32	5.3%
1.3	4.6%
3.3	4.8%
7.3	5.1%
19	4.5%
39	6.4%

	6-Tip	
Level (uIU/ml)	CV whole dat	CV medians
0.02	42.9%	34.1%
2	24.6%	17.9%
20	27.7%	20.8%

Again his number are off. Our precision numbers are instead 8.4%, 3.5% and 4.6%. This is pretty close to the predicate and better in some cases.

Immulite fT4	
Level	CV total
0.51	10.2%
0.85	7.1%
1.13	6.4%
1.49	6.0%
2.91	3.6%
4.82	3.6%

Theranos fT4		
	6-Tip	
Inter mean	whole dat cv	CV medians
1.63	28.8%	14.5%
5.42	11.0%	4.0%
6.68	5.2%	3.9%

Calculations in the report show CVs values of 19.2%, 9.2% and 7.6%.

Immulite TT4	
level	CV total
1.8	11.7%
2.6	10.8%

Theranos TT4		
	6-Tip	
Level	CV whole Dat	CV medians
1.91	16.0%	13.9%

5.2	8.5%				
7	6.1%	3.37	16.0%	14.0%	
8.2	5.6%	15.8	18.3%	14.6%	
13	6.0%				
16	5.6%				

CVs in the report are actually slightly higher than what Tyler has indicated (14.7%, 13.3%, and 12.8%).

Immulite tPSA	Theranos tPSA		
"<4.6% for 3 levels of controls"		6-Tip	
	Level	CV whole Dat	CV medians
	1.4 (ng/ml)	33.8%	13.0%
	3.37 (ng/ml)	17.1%	10.8%
	10.2 (ng/ml)	24.1%	11.8%

Values in the report are 12.4%, 9.4%, and 7.3%.

Diasorin VitD		Theranos VitD		
Level	CV		6-Tip	
		Level	CV whole Dat	CV medians
7.2	5.5%			
14.7	4.2%	11.7 (ng/ml)	18.6%	12.5%
21.7	4.0%	28.7 (ng/ml)	19.1%	9.5%
35	2.9%	73.6 (ng/ml)	12.1%	9.8%
73	3.2%			
62.7	3.1%			
93.6	3.2%			
115	4.2%			

128	4.8%

Oraquick HCV		Theranos HCV	
Sensitivity	99%	Sensitivity	99%
Specificity	100%	Specificity	94%

Values from the report: 7.5%, 6.2%, and 9.3%. Definitely on par with the reported Immulite values.

Immulite TST		Theranos TST		
Level	Total CV		6-Tip	
27.1 ng/dL	24.3%	Level	CV whole Dat	CV medians
86.1 ng/dL	13.0%	90 ng/dL	19.4%	11.6%
152 ng/dL	10.3%	300 ng/dL	12.5%	5.1%
280 ng/dL	9.1%	1,000 ng/dL	17.4%	13.0%
414 ng/dL	8.2%			
991 ng/dL	7.2%			

Furthermore, Theranos has an inherent advantage in these comparisons due to the way we run our precision testing. While our competitors conduct their precision testing over 20 days, we do ours in 5. Accordingly, we can see that our precision experiments are not indicative of longer-term assay performance once we begin running patient samples; our Daily Quality Control failure rate is far greater than would be predicted by our QC reference range calculations, and our internal comparison of Theranos results in proficiency testing yielded less than satisfying results. I am not sure if this analysis has been done, but we should examine our Daily QC results as if it were a prolonged precision experiment to more accurately evaluate long-term assay performance.

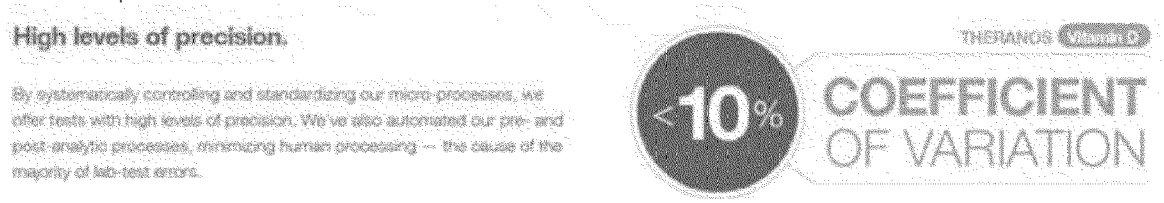
We did conduct all our precision runs in 5 days rather than 20. We did spread it over multiple shifts and operators per day. "20 days" is typical for FDA 510K studies, and for LDTs. Any impact of reagent stability would be reduced by compressing the study to fewer days. If he is referring to what CLIA did last month by splitting the PT sample and running it on Theranos and on the predicate – I explained that this was not the correct procedure, and the results would not be meaningful. Moreover, that the correact procedure of doing AAP was being testing and rolled out. I do not know if he is referring to the recent AAP results for fT4, TSH, and Vit D.

I am sorry if this email sounds attacking in any way, I do not intend it to be, I just feel a responsibility to you to tell you what I see so we can work towards solutions. I am invested in this company's long-term vision, and am worried that some of our current practices will prevent us from reaching our bigger goals. I'm sorry I wasn't able to catch you for a conversation, I know how busy you are, but if you would like to discuss anything I've mentioned in person, I would be more than happy to do so.

Thanks,

Below is the email Tyler sent me with the are media excerpts for which he expressed concerned. Note again that he expressed confusion about how we will be doing PT. I explained our PT and AAP to Tyler at some point, and that what CLIA did for that PT event was not correct. By the way, just last week, I again had to remind Mark and Adam why we are doing the AAP program like I proposed, and why we cannot split samples like they did, and why testing the PT samples on the predicate rather than on our LDTs makes the most sense.

As for finding places where Theranos' test performances are discussed, I am realizing that Theranos does not directly make any public claims that our tests are more accurate, but the authors of articles about Theranos are. The only place I can find Theranos making a claim about test performance is in this banner on our website:



And although it specifically identifies that VitD has <10% CV, there also seems to be an implication that our other tests follow suit.

Here are some other places where it is claimed that Theranos is more precise and more accurate than current methods.
From "This Woman Invented a Way to Run 30 Lab Tests on Only One Drop of Blood"
http://www.wired.com/wiredscience/2014/02/elizabeth-holmes-theranos/
"The results are faster, more accurate, and far cheaper than conventional methods"

From "Small, Fast and Cheap, Theranos Is the Poster Child of Med Tech — and It's in Walgreen's"
http://singularityhub.com/2013/11/18/small-fast-and-cheap-theranos-is-the-poster-child-of-med-tech-and-its-in-walgreens/
"But perhaps lab tests can be made faster, easier and more accurate with a turn-of-the-last-century technology: automation. That's the bet the Silicon Valley company Theranos is making…"
"All of the diagnostic technology is integrated, which increases precision"

From "Secretive Theranos emerging (partly) from shadows"
http://www.bizjournals.com/sanfrancisco/blog/biotech/2013/09/theranos-elizabeth-holmes-walgreens.html
"But the story is scientifically appealing as well because it involves miniaturized technology — microneedles, nanotubes and other teeny-weeny stuff — that could provide more accurate medical information than that collected from traditional blood tests."

From "Breakout in Healthcare: Part I"
http://www.gingrichproductions.com/2013/10/breakout-in-healthcare/
"Theranos has developed technology that can perform all of these tests much more accurately than current laboratories, and with just a few drops of blood…Even more importantly than the greater precision and speed, Theranos has promised to deliver each of its tests for *less than half* the Medicare rate…That is a huge reduction in spending without hurting anybody except Theranos's slower, more expensive, and less precise competitors"

From the Wall Street Journal article "Elizabeth Holmes: The Breakthrough of Instant Diagnosis"
"Theranos's processes are faster, cheaper and more accurate than the conventional methods and require only microscopic blood volumes, not vial after vial of the stuff."
"Another Theranos advance is its testing's accuracy."

In regards to PT, I think most of the confusion about the process is in regards to the legality of how we conducted our PT. The Public Health Service Acts says that "the laboratory agrees to treat proficiency testing samples in the same manner as it treats materials derived from the human body referred to it for laboratory examinations or other procedures in the ordinary course of business". Which it seems we did not do, as patient samples are run on the Theranos system while the PT data we sent out were run on systems like Advia, DiaSorin, Immulite. It additionally prohibits the splitting of a sample to run confirmatory tests in another lab. While we did not necessarily send our samples out to other labs, we did split the samples to run the tests on two different sets of laboratory equipment.

Thanks,

Tyler

From: Elizabeth Holmes
Sent: Thursday, April 10, 2014 4:27 PM
To: Tyler Shultz
Subject: RE: Follow up to previous discussion

Tyler: I'm tied up with people onsite – shoot me an email with anything you wanted to cover so I can be sure it gets addressed, Elizabeth

From: Tyler Shultz
Sent: Thursday, April 10, 2014 3:24 PM
To: Elizabeth Holmes
Subject: Follow up to previous discussion

Hi Elizabeth,

When you have time could I possibly have half an hour to follow up on our previous meeting about the RPR test? I know you are extremely busy, so I wouldn't mind waiting until an evening after the craziness of the work day dies down.

Thanks,

Tyler

EXHIBIT 2

EXHIBIT FILED UNDER SEAL

EXHIBIT 3

EXHIBIT FILED UNDER SEAL

EXHIBIT 4

To: Sami Schneider[sschneider@theranos.com]; Mona Ramamurthy[mramamurthy@theranos.com]
From: Sunny Balwani[/O=THERANOS ORGANIZATION/OU=FIRST ADMINISTRATIVE GROUP/CN=RECIPIENTS/CN=SBALWANI]
Sent: Thur 11/13/2014 4:36:07 AM (UTC)
Subject: RE: clarity on Lab Director roles

thanks appreciate the quick response on this. these 4 candidates will be my focus also so I know we will get this done. I will take time out in real time to interview and do what is needed to close these.

thanks.

From: Sami Schneider
Sent: Wednesday, November 12, 2014 8:34 PM
To: Sunny Balwani; Mona Ramamurthy
Subject: RE: clarity on Lab Director roles

Thank you. Lauren has been supporting these searches. I will pass this info along and make sure the 4 in the queue (and any new candidates) match theses skills/requirements before we schedule.

Sami

Samantha Schneider
Desk 650.470.6184

From: Sunny Balwani
Sent: Wednesday, November 12, 2014 8:33 PM
To: Mona Ramamurthy; Sami Schneider
Subject: clarity on Lab Director roles

Here are some additional details that may help the team. Our goal is to add 4 lab directors in next 3 months. These are in order of priority:

1. We need to hire Lab Director that have experience in larger/R&D labs where assays are developed. Usually pharmaceutical companies, larger labs or Academic institutes. Location Newark.
2. 1 Lab director that has run a smaller/medium size lab and wants to grow. assay development “LDT” experience not required. Location Phoenix.
3. Add one more like #1 above.
4. 1 Lab director that has run a smaller/medium size lab and wants to grow. assay development “LDT” experience not required. Location Newark.

Please let me know if there are any questions.

thanks.

EXHIBIT 5

To: Mona Ramamurthy[mramamurthy@theranos.com]
From: Sunny Balwani[/O=THERANOS ORGANIZATION/OU=FIRST ADMINISTRATIVE GROUP/CN=RECIPIENTS/CN=SBALWANI]
Sent: Fri 11/14/2014 10:22:56 PM (UTC)
Subject: Lab director

Can u please schedule all lab director candidates in California in your queue ASAP. Tomorrow, Saturday Monday will be best.

EXHIBIT 6

To: Suraj Saksena[ssaksena@theranos.com]
From: Sunny Balwani[/O=THERANOS ORGANIZATION/OU=FIRST ADMINISTRATIVE GROUP/CN=RECIPIENTS/CN=SBALWANI]
Sent: Sat 11/15/2014 12:21:31 AM (UTC)
Subject: FW: PhDs as Lab Directors in California

FYI. I will work on getting more details to us and we will get this going asap.

From: Brad Arington
Sent: Friday, November 14, 2014 4:20 PM
To: Elizabeth Holmes
Cc: Sunny Balwani
Subject: PhDs as Lab Directors in California

I've provided below the details from the CLIA regulations and California Business Professions code for PhDs to serve as Lab Director in California.

Briefly, a PhD would (1) need to hold one of the two following California licenses: a Clinical Bioanalyst (2.a. below) or a Clinical Specialist (2.b. below); the licensure application information and process is provided at this link: https://secure.cpshr.us/cltreg/clbcld_examinfo.asp) and (2) be certified by a board approved by HHS (see 1.c.iii below for the current HHS-approved list). I am putting together the information for the board-certifications and will send that separately, but wanted to get this to you in the meantime.

1. CLIA regulations require
   a. □ a state license, when required by the state [Note that there are two types of PhD licensees that can serve as Lab Director]; and
   b. □ for PhDs: hold an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution and be certified and continue to be certified by a board approved by HHS. 42 CFR 493.1443
   c. CMS Guidance:

      i. To qualify as a laboratory director of high complexity testing on or after February 24, 2003, individuals possessing a Ph.D. must be board certified by an approved board.

      ii. "Certified" means the individual has completed all the designated board's requirements, including the examination.

      iii. Currently approved boards are:

         1. American Board of Bioanalysis (ABB),
         2. American Board of Clinical Chemistry (ABCC),
         3. American Board of Forensic Toxicology (ABFT),
         4. American Board of Histocompatibility and Immunogenetics (ABHI),
         5. American Board of Medical Genetics (ABMG),
         6. American Board of Medical Laboratory Immunology (ABMLI),
         7. American Board of Medical Microbiology (ABMM),
         8. National Registry for Clinical Chemists (NRCC), or other board deemed comparable by HHS. NOTE: ABFT and NRCC also certify non-doctorial individuals; however, the director of high-complexity testing must have a doctoral degree.

2. California PhD licensees that can serve as Lab Directors
   a. Clinical Bioanalyst

      i. Definition: a person licensed under Section 1260 (see licensure requirements below) to engage in clinical laboratory practice and direction of a clinical laboratory. (BPC 1203)

ii. Functions and Roles: A person licensed as a clinical laboratory bioanalyst and qualified under CLIA **may perform clinical laboratory tests or examinations classified as of high complexity under CLIA** and the duties and responsibilities of a **laboratory director**, technical consultant, clinical consultant, technical supervisor, and general supervisor, as specified under CLIA, in the specialties of histocompatibility, microbiology, diagnostic immunology, chemistry, hematology, immunohematology, genetics, or other specialty or subspecialty specified in regulations adopted by the department. (BPC 1203)

iii. Licensure Requirements:

- Business Professions Code section 1260:
  - ☐ Master's degree or higher in chemical, physical, biological or clinical laboratory sciences; Specific educational requirements are provided in 17 CCR 1030(b).
  - ☐ Minimum four year's experience as a licensed CLS, performing clinical laboratory work embracing the various fields of clinical laboratory activity in a clinical laboratory approved by the department
  - ☐ Successfully pass a written examination and an oral examination conducted by the department or a committee designated by the department indicating that the applicant is qualified. (Note that the examination requirements are in 17 CCR 1030(a).)
    - Alternative: The department may issue a license without conducting a written examination to an applicant who has passed a written examination of a national accrediting board having requirements that are, in the determination of the department, equal to or greater than those required by this chapter and regulations adopted by the department.

b. Clinical Chemist, Clinical Microbiologist, Clinical Toxocologist, Clinical Cytogeneticist, Clinical Genetic Molecular Biologist, Oral and Maxillofacial Pathologist

i. Definition: any person licensed by the department under Section 1264 (see licensure requirements below) to engage in, or supervise others engaged in, clinical laboratory practice limited to his or her area of specialization or to direct a clinical laboratory, or portion thereof, limited to his or her area of specialization to engage in clinical laboratory practice. (BPC 1207)

ii. Functions and Roles: Such a licensed person who is qualified under CLIA **may perform clinical laboratory tests or examinations classified as of high complexity under CLIA**, and the duties and responsibilities of a **laboratory director**, technical consultant, clinical consultant, technical supervisor, and general supervisor, as specified under CLIA, limited to his or her area of specialty or subspecialty, and shall only direct a clinical laboratory providing service within those specialties or subspecialties. (BPC 1207)

iii. Licensure Requirements:

- Business Professions Code 1264
  - ☐ Master of science or doctoral degree in the specialty for which the applicant is seeking a license and who has met such additional reasonable qualifications of training, education, and experience as the department may establish by regulations. The education shall have been obtained in one or more established and reputable institutions maintaining standards equivalent, as determined by the department, to those institutions accredited by an agency acceptable to the department. Graduate education must include 30 semester hour of coursework in the applicant's specialty
  - ☐ One year of training in his or her specialty in a clinical laboratory acceptable to the department and three years of experience in his or her specialty in a clinical laboratory, two years of which must have been at a supervisory level. BPC 1264 (a) and 17 CCR 1030.5
  - ☐ The written and oral examination requirements are provided in 17 CCR 1030.5. Out of state examinations may be acceptable to the department. BPC 1264(b)

Brad Arington
Theranos, Inc.
Senior Regulatory Counsel
Direct: (650) 856-7304
Cell: [redacted]

EXHIBIT 7

To: Suraj Saksena[ssaksena@theranos.com]; Brad Arington[barington@theranos.com]
Cc: Elizabeth Holmes[eholmes@theranos.com]
Bcc: Daniel Young[dyoung@theranos.com]
From: Sunny Balwani[/O=THERANOS ORGANIZATION/OU=FIRST ADMINISTRATIVE GROUP/CN=RECIPIENTS/CN=SBALWANI]
Sent: Mon 11/17/2014 10:06:00 PM (UTC)
Subject: RE: time to meet

Brad.

I briefly spoke with Suraj and he already is a member of the American Society of Cell Biologists and also a fellow of AHA. I think both of these should qualify for him to apply for CLIA Lab Director licence for high complexity – not just moderate. can you meet with him and understand his qual and fast track him for high complexity app also (in addition to others for moderate).

thanks.

From: Suraj Saksena
Sent: Monday, November 17, 2014 2:04 PM
To: Brad Arington; Sunny Balwani
Subject: time to meet

Hi Brad,

Sunny would like for me to touch base with you today about some of my qualifications in addition to a PhD in Biochemistry. Please let me know when I can stop by.

Thanks,
Suraj

EXHIBIT 8

To: Suraj Saksena[ssaksena@theranos.com]
From: Sunny Balwani[/O=THERANOS ORGANIZATION/OU=FIRST ADMINISTRATIVE GROUP/CN=RECIPIENTS/CN=SBALWANI]
Sent: Tue 11/18/2014 7:11:35 PM (UTC)
Subject: Re: Lab Personnel Update -- A/C Privileged

We need high complexity in California. You should begin this path. It won't be that difficult.

Arizona is clearly very easy for moderate complexity and u r already qualified for that so we are going to pursue that now.

Thanks.

On Nov 18, 2014, at 11:57 AM, Suraj Saksena <ssaksena@theranos.com> wrote:

> Hi Sunny,
>
> I spoke with Brad at length yesterday and it seems that the CA path may not be as clear cut. AZ seems a lot more straightforward. Just out of curiosity, can we consider the possibility of making AZ our 'high complexity' lab and making CA the 'medium complexity' lab. AZ certainly seems more doable for both medium and high complexity.
>
> Thanks,
> Suraj
>
> ---
>
> **From:** Sunny Balwani
> **Sent:** Tuesday, November 18, 2014 10:25 AM
> **Subject:** Fwd: Lab Personnel Update -- A/C Privileged
>
> Begin forwarded message:
>
> > **From:** Brad Arington <barington@theranos.com>
> > **Date:** November 18, 2014 at 10:14:37 AM PST
> > **To:** Sunny Balwani <sbalwani@theranos.com>
> > **Subject: Lab Personnel Update -- A/C Privileged**
> >
> > Here is a summary of the research that I've done on the board certifications and from my discussion with Suraj. I know it's not that brief, but the requirements are generally fairly complicated. I will send you a separate email about the AZ question.
> >
> > Unfortunately, the American Society for Cell Biology is not an accrediting organization, but rather an association of research scientists, students, educators (high school, undergraduate, and graduate level), and technicians who have education or research experience in cell biology. So Suraj's membership does not satisfy the certification requirement by the HHS-approved boards.
> >
> > I have highlighted the major requirements for each below and timing when the examinations are offered where available on the board's website. Bars appear to be pretty high, except for the National Registry of Certified Chemists – see the first one highlighted in yellow.
> >
> > - NRCC – National Registry of Certified Chemists
> >   - There are very frequent test dates. There are not a lot of details about this path on the website, but it seems to me that this may be the least burdensome path to meeting the CLIA requirement.
> >   - PhD with 24 semester hours in chemistry and 8 in another science
> >   - Minimum 2 years of clinical laboratory experience dealing with human specimens

for diagnostic and/or therapeutic purposes, i.e., in a CLIA lab and not research.

- Here is the website: http://www.nrcc6.org/index.html

? ABB – American Board of Bioanalysis – there are two certifications that would be available for Lab Director, the others are specific to forensic and embryolic pathology
  - Exam is offered in May and October
  - One year = 2080 hours of documented experience
  - Bioanalyst Clinical Lab Director Certification (Generalist) –
    - ✍ 4 years total documented experience, including 4 years experience in 3 out of 5 specialties (Chemistry, Diagnostic Immunology, Hematology, Microbiology, and Molecular Diagnostics) and 2 years of the 4 must be directing or supervising high complexity testing in a clinical setting. Up to 2 years of the 4 of the experience may be met by alternative means, including certain work in an IVD company, but this doesn't replace the 2-year supervising high complexity testing requirement.
    - ✍ Exam includes the General Knowledge, plus 3 specialty sections
  - High Complexity Clinical Laboratory Director
    - ✍ 4 years total documented experience on human specimens, with 2 years of the 4 directing or supervising high complexity testing in a clinical setting. Up to 2 years of the 4 of the experience may be met by alternative means, including certain work in an IVD company, but this doesn't replace the 2-year supervising high complexity testing requirement.
    - ✍ Pass the ABB Exam in General Knowledge and one of the specialty sections.

? ABCC – American Board of Clinical Chemistry
  - Exams offered in February (Nov 1st application deadline) and July.
  - There are three types of accreditations: Clinical Chemistry, Toxicological Chemistry and Molecular Diagnostics.
  - Each generally requires 5 years' full-time diverse professional experience in the specialty obtained subsequent to the conferral of the PhD and in laboratories or institutions maintaining standards acceptable to the Board. There are some shortened requirements for those who have post-doc training in programs accredited by the Commission on Accreditation in Clinical Chemistry.

? ABMLI – American Board of Medical Laboratory Immunology
  - Did not say on the website when exams are offered.
  - There are three paths to accreditation.
    - ✍ One requires enrollment for 2 years in "CPEP" approved programs run by organizations like the Mayo clinic and Beth Israel in Boston.
    - ✍ Second path requires 1-year post doc training and 2 years of specific experience
    - ✍ Third path requires 3 years of post doc experience
      - ? Post doc Training: Postdoctoral training must be gained in a setting where a broad range of immunologic procedures are performed under the direction of a qualified immunologist. This setting should be in conjunction with either a clinically oriented immunology service or a basic research laboratory utilizing multiple procedures applicable to medical laboratory immunology. Candidates must spend a minimum of 30 hours per week in this setting.
      - ? Post doc Experience: minimum of 30 hours per week spent in a laboratory actively involved in medical laboratory immunology as defined by this Board and should involve familiarity and direct experience with a broad range of diagnostic procedures, including

interpretation and laboratory management, as well as supervisory duties.
    - Minimum percentages of specific activities: Administrative and management activities (5%), Diagnostic and clinical service (50%), Research (5%), Teaching of basic and clinical laboratory immunology (5%).
    - Experience falling outside of the described categories will be scrutinized for acceptability by the Board.
- ABMM – American Board of Medical Microbiology
    - Did not say on the website when exams are offered.
    - There are two paths to accreditation.
        - One requires enrollment for 2 years in "CPEP" approved programs run by organizations like the Mayo clinic and Beth Israel in Boston.
        - Second path requires 3 years of post doc experience
            - Post doc Experience: Appropriate experience requires an ongoing relationship with a clinical, public health, reference, or other microbiology laboratory that includes a diagnostic service component such that the candidate has devoted at least 75% of his/her time to management, clinical, and administrative activities during the three years of experience..
                - Minimum percentages of specific activities: Responsibilities and skills in the clinical laboratory (50-65%), Interaction with healthcare providers (15-30%), Management and administrative skills (10-20%), Research (0-25%) and Teaching (0-25%)
                - Experience in which more than 25% of time is spent on research, teaching, grant writing, or test development does not satisfy the experience requirement.

There are other boards that I can look into, but they do not cover any of the testing performed in our lab currently, such as genetic testing, forensic toxicology, histocompatibility and immunogenetics, public health directors, etc. There is also a 24-month program accredited by the Commission on Accreditation in Clinical Chemistry through which accreditation can be obtained.

Also note that for California, the PhD Lab Director of a high-complexity lab has to be accredited by one of the Boards and have a California license – either the Clinical Bioanalyst or one of the Limited Specialist where the Lab Director is limited to that specialty, such as Clinical Chemist. California accepts national accreditation exams for all the types of Lab Directors except for Clinical Bioanalyst and Clinical Microbiologist. Those are California administered exams. California also may have more stringent training and experience requirements than the boards have in order to obtain the applicable license.

Brad Arington
Theranos, Inc.
Senior Regulatory Counsel
Direct: (650) 856-7304
Cell:

EXHIBIT 9

To: Sunny Balwani[sbalwani@theranos.com]
From: Suraj Saksena[/O=THERANOS ORGANIZATION/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=SURAJ SAKSENA]
Sent: Fri 5/8/2015 5:48:16 PM (UTC)
Subject: RE: NRCC exam results

Thanks Sunny. My biggest worry was disappointing your trust in me. I am glad I delivered.

Best
Suraj

From: Sunny Balwani
Sent: Friday, May 08, 2015 10:45 AM
To: Suraj Saksena; Elizabeth Holmes
Subject: RE: NRCC exam results

congratulations. outstanding focus.

From: Suraj Saksena
Sent: Friday, May 08, 2015 10:43 AM
To: Sunny Balwani; Elizabeth Holmes
Subject: FW: NRCC exam results

Hi Sunny & Elizabeth,

Please see below regarding the exam.

Thanks for the unconditional support I have received from the two of you over the last 3 months as I prepared for this exam.

Best
Suraj

From: Russ Phifer [mailto:rphifer@nrcc6.org]
Sent: Friday, May 08, 2015 8:28 AM
To: Suraj Saksena
Subject: NRCC exam results

Suraj – I am pleased to inform you that you have passed the NRCC Clinical Chemist exam and are now fully certified. We will mail your certificate shortly. Please let me know if there is anyone you need to have officially notified. Congratulations – you had the highest score I have seen on that exam in my four years in this position.

Russ

Russ Phifer
Executive Director
National Registry of Certified Chemists
125 Rose Ann Lane
West Grove, PA 19390
610-322-0657
800-858-6273 FAX
rphifer@nrcc6.org
www.nrcc6.org

EXHIBIT 10

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

IN RE:	)	
	)	Civil Action No.
THERANOS INC.,	)	No. 2:16-cv-2138-HRH
LITIGATION,	)	

*** CONFIDENTIAL ***

VIDEOTAPED DEPOSITION OF WADE MIQUELON

August 9, 2019

Chicago, Illinois

REPORTED BY:
Sheri E. Liss,
CSR, RPR, CRR, CLR

JOB NO. 10057960

Foundation.
BY THE WITNESS:
A. I don't recall.
BY MS. HOWARD:
Q. Did you have any understanding of how Theranos when it was partnering with Walgreens was addressing throughput issues as you were rolling out more and more testing locations?
MR. LEVINE: Objection. Foundation.
BY THE WITNESS:
A. I was not involved in that.
BY MS. HOWARD:
Q. Did you have any understanding as to whether Theranos was using commercial testing equipment?
A. I had a limited understanding.
Q. And what was your understanding?
A. My understanding was that two things, one is that they had some commercial equipment which was used to be able to do, again, I don't know if calibration is the right word, but this back and forth checking of traditional equipment versus Theranos equipment. And I also recall that Sunny and Elizabeth saying that when we started up that there might always be some tests that require venous

puncture by their very nature but over time this should be very, very small.

Q. And what was your understanding about how those tests that required venous puncture would be analyzed?

A. My understanding is the ones that required venous puncture would be done on a traditional lab test machine or perhaps outsourced to a lab. They would not be run on the Edison.

MS. HOWARD: I don't have any further questions. Thank you.

MR. LEVINE: None here.

MS. SEEGER: We'll reserve signature.

MS. GARDNER: Plaintiffs object to three exhibits that don't have Bates numbers for this litigation, and request that Balwani's counsel substitute and produce copies or meet an confer about the issue.

MS. HOWARD: For clarity, those are Exhibit Nos. 285, 286 and 289; is that correct?

MS. GARDNER: Yes, that is correct.

THE VIDEOGRAPHER: This concludes the deposition. The time is 4:38. Off the record.

(Whereupon, the proceedings were concluded.)

I further certify that I am not counsel for nor in any way related to any of the parties to this suit, nor am I in any way interested in the outcome thereof.

I further certify that this certificate applies to the original signed and certified transcripts only. I assume no responsibility for the accuracy of any reproduced copies not made under my control or direction.

IN TESTIMONY WHEREOF I have hereunto set my hand this 19th day of August, 2019.

Sheri E. Liss, CSR, RPR, CRR, CLR